REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested.

The Examiner's attention is drawn to the attached Ph.D. thesis by Nick Polydorides (a Ph.D. student of Professor McCann, who is a named co-inventor in this application). It has now become apparent that this thesis was made available before the claimed priority date of the present application. It is understood that this thesis was made available on the Internet on March 11, 2003. Form PTO/SB/08a listing the thesis is also attached, together with the IDS fee for this stage of prosecution.

The rejection of claims 22-26, 28, 33, 36, 38-40 and 42 under 35 U.S.C. §103 as allegedly being made "obvious" based on Boone '142 in view of Trivedi '359 and John '335 is respectfully traversed.

The rejected claims require injecting electrical current from an external source between a pair of electrodes at a body surface and collecting the resulting voltage measurements between pairs of surface electrodes. This is a procedure that is widely practiced to carry out imaging by the techniques known as Electrical Impedance Tomography (EIT). As those skilled in the art will understand, the claims are therefore directed to "active" processes capable of characterizing structures/events deep within the body under examination for example, the technique can be made more sensitive by increasing the magnitude of the current that is passed through the body under

examination, or by re-arranging the relative positions of current-injection and voltage-measurement electrodes.

By contrast, electroencephalography (EEG) and electrocardiology (ECG) are entirely "passive" processes which monitor body surface current and/or voltages which naturally occur due to physiological activity within the body.

Those having skill in the art recognize that there are fundamental and stark differences between the claimed active processes on the one hand, and the passive EEG/ECG techniques on the other hand. As explained in more technological detail by Dr. Pomfrett in the attached declaration under 37 C.F.R. §1.132, those skilled in the art would clearly not find it "obvious" to transport teachings from one measurement domain to the other – and especially not in some willy-nilly fashion as the Examiner's comments seem to suggest.

Dependent claim 23 actually requires production of an image based on the set of voltage measurements, the image representing the distribution of impedance within the body being actively measured. Indeed, as will be explained in more detail below, it is not even technically feasible to "combine" the EEG Trivedi/John systems with the EIT Boone system. Still further, even if such a "combination" were attempted without regard to technological facts (i.e., *arguendo*), then one still would not arrive at the rejected claims.

Contrary to the Examiner's assertion, a person skilled in the art simply would not consider combining features of an EEG system (such as the systems of Trivedi and John) with an EIT system (such as that of Boone). This is explained in Dr. Pomfrett's attached declaration. In particular, the fundamentally different nature of EIT measurements and EEG measurements is such that techniques used in one measurement methodology cannot be routinely applied to the other. Indeed, in general terms, while many different systems for monitoring brain activity are known, it cannot be the case that techniques applied in the context of one system would be obvious to apply to any and all other methods, and indeed, the systems are inherently incompatible for reasons given in Dr. Pomfrett's declaration.

Furthermore, each of claims 22, 38 and 42 requires that a set of voltage measurements be collected over a predetermined measurement period and that the predetermined measurement period be initiated after a predetermined delay based upon a neurological model following occurrence of a sensory stimulus. This is not the case in any of the cited prior art. Thus, even if all the cited art is somehow (illogically) "combined," one still does not have applicants' claimed invention.

The Examiner asserts that Trivedi teaches monitoring a sensory stimulus response during a predetermined measurement period initiated after a predetermined delay following a sensory stimulus, based upon a neurological model. This is incorrect.

The Trivedi "Montage Analysis" section is directed to identification of features of interest in data, such as epileptic spikes (25:43-46). An iterative process for identifying a feature of interest such as a peak having a particular shape in the data is described (26:23-26). The "Montage Analysis" section is, therefore, concerned with identifying parts of the data based upon the data itself.

The Examiner appears to assert that such selection implies an inherent time delay after stimulus application. However, the time delay between application of a stimulus and the time at which a feature occurs in the data cannot reasonably be said to be a delay selected based upon a neurological model. The inherent time delay of Trivedi is based upon the fact that a particular type of peak, such as a peak having a particular shape, happens to occur at that particular time. To determine the time delay involved, one must also necessarily analyze the data from some earlier time point.

On the contrary, applicants' claim 22 explicitly requires that the predetermined delay is based upon a neurological model. That is, the set of voltage measurements is collected after a delay based upon *a priori* knowledge of operation of the nervous system as represented by a neurological model. This is clearly something very different from processing particular data and then later seeking to identify particular patterns in that data – based on characteristics of the data itself. This is what Trivedi does.

There is nothing in Trivedi to teach (or suggest) collecting a set of measurements over a predetermined measurement period, the predetermined measurement period being initiated after a predetermined delay (based upon *a priori* knowledge of a neurological model) following occurrence of a sensory stimulus.

The Examiner asserts that it would have been obvious to combine Boone and Trivedi with John to arrive at the claimed invention. The Examiner asserts that John teaches comparing collected measurements with reference measurements. This is incorrect. While John teaches that data is analyzed in a computer system to extract numerical descriptors which are compared to a set of norms (paragraph [0011]), it is not true that the comparison of John teaches a comparison to determine normal or abnormal response of the nervous system as recited in applicants' claims 22, 38 and/or 42. None of the cited documents teaches the comparison of collected measurements with reference measurements to determine normal or abnormal response.

Furthermore, the collected voltage measurements that are compared with reference measurements as required by applicants' claims 22, 38 and 42 are a set of voltage measurements collected over a predetermined measurement period initiated after a predetermined delay (which is based upon a neurological model) following occurrence of the sensory stimulus. The inventors have realized that by comparing voltage measurements that have been carefully collected based upon a neurological model, very specific time-based reactions to sensory stimulus can be analyzed. By carefully

selecting the delay based upon a neurological model, specific parts of the nervous system can be checked for normal or abnormal response since particular parts of the brain react at particular times after stimulus application, as is known from an *a priori* model.

The measurements of John that are compared with reference measurements are measurements denoting an averaged value indicating a general response of the brain to a stimulus. This can be seen from John at paragraph [0047] which states that brain waves measured at application of a stimulus are measured and averaged to give an "Average Evoked Response." Paragraph [0049] provides an alternative where narrow-band FFT is used to compare power in an EEG when the stimulator is "on" compared with when the stimulator is "off." Indeed, this disclosure of John emphasizes the fundamental difference between (a) processing of measurements obtained at a particular time delay after stimulus application and (b) obtaining an average measurement – which is inherent in EEG-type systems.

John, therefore, is concerned with a comparison of a general response to a stimulus of a patient with a reference general response. John is not concerned with comparing (a) a response of a particular part of a nervous system, determined using measurements captured in a predetermined measurement period initiated after a predetermined delay which is based upon a neurological model, with (b) reference measurements as required by applicants' claims 22, 38 and 42.

As set out above, a combination of the EEG systems of Trivedi and John with the EIT system of Boone is technologically not feasible. That is, the fundamental difference between the nature of measurements undertaken in an EEG system and the nature of measurements in an EIT system is such that the alleged combination is impossible and not one that a skilled person would attempt to make. However, even if such a combination were attempted *arguendo*, a skilled person would nevertheless not arrive at the method of any of applicants' claims 22, 38 and 42.

The Examiner's other rejections (e.g., of claims 32, 41 and 43) based upon a combination of Trivedi with other documents is also fundamentally flawed. For reasons such as those set out above, Trivedi does not teach the features alleged by the Examiner.

Additionally, claim 32 requires that the predetermined delay be selected on the basis of a neurological model and a predetermined part of the nervous system for which a response is to be monitored. In the office action, the predetermined part of the nervous systems is said to be the brain. Notwithstanding that, for the reasons set out above, none of the cited prior art is concerned with a delay which is selected on the basis of a neurological model – and it should further be noted that none of the cited prior art is concerned with a delay which is based upon a predetermined part of the nervous system for which a response is to be measured. That is, claim 32 is concerned with the situation in which part of the nervous system is selected and, based upon this selection,

a delay is determined. Such determination is neither taught nor suggested by any of the cited prior art.

Given such fundamental deficiencies of all of the cited references as already discussed, it is not necessary at this time to discuss additional deficiencies of this trio of references with respect to other aspects of the rejected claims. Suffice it to note that, as a matter of law, it is impossible to support even a *prima facie* case of "obviousness" unless the cited prior art teaches each and every feature of the rejected claims.

The rejection of claims 29-31 and 41 under 35 U.S.C. §103 as allegedly being made "obvious" based on Boone/Trivedi/John now in further view of a fourth reference to Yamazaki '825 is also respectfully traversed.

Fundamental deficiencies of the first three references have already been noted above for parent claim 22 of dependent claims 29-31. Yamazaki does not supply those deficiencies.

With respect to independent claim 41, Boone/Trivedi/John also suffers serious deficiencies such as noted above for other independent claims. And, as already noted, Yamazaki does not supply even those deficiencies.

Furthermore, Yamazaki only uses a single electrode 21 (Fig. 1) or 47 (Fig. 6) and thus inherently teaches away from applicants' claimed invention. This is yet another indicator that the Examiner has engaged in undue "hindsight" when trying to find bits

and pieces of applicants' invention here and there in numerous references that were apparently discovered using text searching algorithms with applicants' own claims being used as a hindsight template for the search process.

The rejection of claims 32, 34 and 37 under 35 U.S.C. §103 as allegedly being made "obvious" based on Boone in view of Trivedi is also respectfully traversed.

Although the Examiner here omits the John reference, the same fundamental error is present when the Examiner attempts to "combine" the Boone EIT teaching with the Trivedi EEG techniques. Once again, even if the teachings of Boone and Trivedi are "combined" *arguendo*, one still fails to find any teaching or suggestion of the applicants' claimed invention. For example, note that both independent claims 32 and 37 also require the predetermined delay to be selected on the basis of a neurological model of the nervous system, etc.

Given such fundamental deficiencies of these references with respect to features already discussed, it is not necessary at this time to explain further deficiencies of this allegedly "obvious" combination of references with respect to other aspects of the claimed invention. Once again, suffice it to note that, as a matter of law, it is impossible to support even a *prima facie* case of "obviousness" unless the cited art at least teaches or suggests each and every feature of the rejected claims.

The rejection of claim 35 under 35 U.S.C. §103 as allegedly being made "obvious" based on Boone in view of Polydorides is also respectfully traversed.

It should be noted that claim 35 depends from claim 32 – and the Examiner has for some reason found it necessary to attempt "combining" Boone and Trivedi to arguably meet the limitations of parent claim 32.

Here, with dependent claim 35, the Examiner dispenses with Trivedi altogether and relies upon the "combination" of Boone and Polydorides. Although both Boone and Polydorides do deal with EIT techniques, the combination proposed by the Examiner still fails to teach or suggest the features of applicants' claim 32/35.

It will be noted that independent parent claim 32 already requires the predetermined delay to be selected on the basis of a neurological model, etc. Dependent claim 35 adds the further limitation that the region and/or areas are selected such that sensitivity of the derived impedance measurements to changes in the predetermined part of the nervous system is maximized. The Examiner admits that Boone has no such teaching.

To supply this admitted deficiency, the Examiner relies upon Polydorides at I. INTRODUCTION (paragraphs 1 and 2) and at page 601, col. 1, paragraph 2. Among other things, the Examiner alleges that Polydorides includes a teaching that causes a selection of regions and/or areas to be made on the "basis of a neurological model of

the nervous system" – such that sensitivity of derived impedance measurements is maximized.

Even if the additional features, *per se*, of dependent claim 35 are assumed to be present in Polydorides, this still fails to teach the substance of parent claim 32 – about which Boone is also deficient. Therefore, even if these two references are combined, *arguendo*, there is still no teaching or suggestion of the invention claimed in claim 35.

If the Examiner believes that somewhere in Boone/Polydorides there is a teaching or suggestion of the claim 32/35 requirements, *inter alia*, for a predetermined part of the nervous system to be identified – and then for a predetermined voltage measurement delay to be selected based on a neurological model of the nervous system and that predetermined part of the nervous system for which a response is monitored – then the Examiner is respectfully requested to more particularly point out where such teaching or suggestion might be found. As noted above, it is not found in Boone. Nor does it appear to be found in Polydorides. That is, even if it is assumed *arguendo* that Polydorides may teach placement of electrodes for maximizing desired measurement sensitivity (in the context of the Polydorides teaching), this still fails to teach or suggest the invention of claim 32/35.

The rejection of claim 43 under 35 U.S.C. §103 as allegedly being made "obvious" based on Boone/Trivedi/Polydorides is also respectfully traversed.

For reasons already noted, it is not believed "obvious" to combine the EEG techniques of Trivedi with the EIT techniques of Boone/Polydorides. Furthermore, as previously noted, applicants are not merely imaging the brain's white matter (Boone and/or Polydorides). Instead, applicants' claim 43 provides an iterative process as a function of different initial time delays so as to derive a time sequence of images for revealing nervous system responses to a predetermined sensory stimulus in different parts of the subject's brain.

The rejection of claim 27 under 35 U.S.C. §103 as allegedly being made "obvious" based on Boone/Trivedi/John in further view of Vauhkonen is also respectfully traversed.

Claim 27 depends from independent claim 22. Fundamental deficiencies of Boone/Trivedi/John have already been noted above with respect to parent claim 22. Vauhkonen does not supply those deficiencies.

While of course some prior art may be found in some context using a "Kalman" filter, applicants have never claimed to have invented a "Kalman" filter *per se*. Furthermore, merely adding a Kalman filter to the EIT teachings of Boone would not arrive at the applicants' claimed invention. Indeed, for reasons already noted above, even if all four of these references were somehow arguably "combined," one is still left without a teaching or suggestion of the applicants' invention.

Attention is also drawn to new independent claims 44-46.

New claim 44 is based upon original claim 32, but has been altered to make it clear that the response of a predetermined part of a subject's brain is being monitored. This makes it clear that the recited "part" of the nervous system is not the whole brain itself.

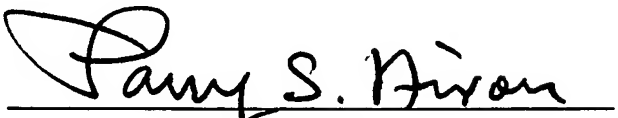
New claim 45 makes it clear that the set of voltage measurements is collected over a predetermined measurement period which is initiated after a predetermined delay following occurrence of the stimulus with no measurements being collected during the delay. This is clearly shown in the specification, for example, with reference to Fig. 2 where a stimulus is applied and a time elapses before current is injected and voltages are measured. There is no such concept of a delay during which no measurements are obtained in any of the cited prior art.

New claim 46 is limited to monitoring the response of the lateral geniculate nucleus of a subject's brain. The lateral geniculate nucleus is located relatively deep within the brain and, therefore, activity of the lateral geniculate nucleus cannot be detected using EEG-type techniques. Thus, it is clear that when considering monitoring of the lateral geniculate nucleus, the skilled person could not possibly consider EEG-type devices as taught by Trivedi and John.

Accordingly, this entire application is now believed to be in allowable condition, and a formal notice to that effect is earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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